

Docket No.: 147303US0FWC I

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COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

RE: Application Serial No.: 08/192,800

Applicants: Tetsuji SUDOH, et al. Filing Date: February 7, 1994

Timing Date: Teordary 7, 1994

For: PHYSIOLOGICALLY ACTIVE POLYPEPTIDE AND

DNA

Group Art Unit: 1635
Examiner: S. MCGARRY

SIR:

Attached hereto for filing are the following papers:

Petition under 37 C.F.R. §1.181(a) Requesting Withdrawal of the Holding of Abandonment; Exhibit 1: Copy of Docketing Report; Exhibit 2: Copy of Our Amendment Previously Filed on September 2, 2004

The Office is hereby authorized to charge deposit account 15-0030 for any necessary fees for such a petition. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C. Norman F. Oblon

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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :

TETSUJI SUDOH, ET AL. : EXAMINER: S. MCGARRY

SERIAL NO: 08/192,800

FILED: FEBRUARY 7, 1994 : GROUP ART UNIT: 1635

FOR: PHYSIOLOGICALLY ACTIVE POLYPEPTIDE AND DNA

PETITION UNDER 37 C.F.R. §1.181(a) REQUESTING WITHDRAWAL OF THE HOLDING OF ABANDONMENT

OFFICE OF PETITIONS 600 DULANY STREET MADISON WEST BUILDING ALEXANDRIA, VA 22313

SIR:

Responsive to the Notice of Abandonment dated May 2, 2005, Applicants respectfully Petition that the Office withdraw the holding of abandonment and restore the present application to pending status.

The Notice of Abandonment is believed to have been issued in error because the Official Action mailed on June 2, 2004 (hereinafter referred to as "the Official Action") was a non-final rejection and a complete response to that Official Action was timely filed on September 2, 2004 (hereinafter referred to as "the response"). Therefore, the application was in compliance with the provisions of 37 C.F.R. §1.111.

Our firm received the Official Action on June 3, 2004. It is the understanding of the undersigned that our firm's docketing section questioned whether the Official Action was actually a final rejection. A staff member of our firm (M. Jojic) contacted the Examiner by telephone on June 9, 2004 to determine the status of the Official Action. As demonstrated by

the entry in our firm's electronic docketing database, submitted herewith as Exhibit 1, the Examiner informed our staff member that the rejection was a non-final rejection. From this point on, our firm treated the Official Action as a non-final rejection.

As noted above, the response to the Official Action was filed on September 2, 2004. A copy of the response is submitted herewith as Exhibit 2. On September 17, 2004, our firm received an Advisory Action which had been mailed out from the PTO on September 16, 2004. The Advisory Action indicated, *inter alia*, that the amendments submitted in the response would not be entered.

The undersigned, surprised to receive a Advisory Action in an application which was assumed to be under non-final rejection, contacted the Examiner by telephone. The Examiner informed the undersigned that the Advisory Action was issued in error and that he would enter our amendments and take the next step in prosecution. A letter signed by the undersigned reporting this development was sent to the Applicants' Japanese counsel by facsimile on September 22, 2004. A copy of that letter is available upon request.

On May 3, 2004, our firm received a Notice of Abandonment which had been mailed from the PTO the previous day. The Notice of Abandonment indicates that the application is abandoned due to "Applicant's failure to timely file a proper reply to the Office letter mailed on 16 September 2004."

The undersigned contacted the Examiner by telephone over the time period of May 4-11, 2004 to discuss the situation. The Examiner left a voicemail for the undersigned on May 11, 2004 in which he explained that it appears that he did not take the necessary steps to have the response filed on September 2, 2004 entered, apologized for the oversight, and suggested that filing a suitable petition was the best way to proceed, in view of the fact that a Notice of Abandonment has been issued.

In view of the facts that our firm treated the Official Action as a non-final rejection

based on the representations of the Office as set forth above and a complete response to that

Official Action was timely filed, Applicants respectfully submit that the application is in

compliance with the provisions of 37 C.F.R. §1.111. Accordingly, Applicants respectfully

request that the Office (1) grant the present petition, (2) withdraw the holding of

abandonment, (3) enter the amendments and remarks submitted with the response filed on

September 2, 2004, and (4) forward the file to the Examiner for further prosecution on the

merits.

In the alternative, and contingent on the denial of the petition for withdrawal of the

holding of abandonment as set forth above, the Office is requested to treat this paper as a

petition under 37 C.F.R. §1.137(a) for unavoidable abandonment. The discussion above is

believed to satisfy the requirement under 37 C.F.R. §1.137(a)(3). The Office is authorized to

charge deposit account 15-0030 for any necessary fees for such a petition.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,

MAIER & NEUSTADT, P.C.

Norman F. Oblon

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(OSMMN 06/04)

James J. Kelly, Ph.D. Attorney of Record

Registration No. 41,504

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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF

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TETSUJI SUDOH, ET AL.

: EXAMINER: S. MCGARRY

SERIAL NO: 08/192,800

FILED: FEBRUARY 7, 1994

: GROUP ART UNIT: 1635

FOR: PHYSIOLOGICALLY ACTIVE POLYPEPTIDE AND DNA

AMENDMENT

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

SIR:

Responsive to the Office Action dated June 2, 2004, Applicants respectfully request reconsideration of the above-identified application in view of the following amendments and remarks.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

A discussion of the **Support for the Amendments** begins on page 5 of this paper.

Remarks begin on page 6 of this paper.



IN THE CLAIMS

The status of each claim of the present application is listed below.

Claims 1-35: Canceled.

36. (Previously Presented) A method of producing a cDNA encoding a human brain natriuretic peptide, comprising:

hybridizing a probe having a DNA sequence encoding a part of a porcine brain natriuretic peptide to a human cDNA library;

selecting a positive clone; and

isolating the cDNA of said positive clone,

wherein said probe is obtained by digesting a complete or incomplete cDNA clone encoding porcine brain natriuretic peptide with endonucleases XhoI and RsaI.

37. (Previously Presented) The method of Claim 36, wherein said probe is labeled.

Claims 38-61: Canceled.

62. (New) An isolated polypeptide having an amino acid sequence which consists of the following amino acids:

H-Gly Ser Gly Cys Phe Gly Arg Lys Met Asp Arg Ile Ser Ser

Ser Ser Gly Leu Gly Cys Lys Val Leu Arg Arg His-OH
which is in the form of an acid addition salt, wherein the acid is selected from the group
consisting of sulfuric acid, formic acid, citric acid, fumaric acid and maleic acid.



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- 63. (New) The isolated polypeptide of Claim 62, wherein the acid is selected from the group consisting of citric acid, fumaric acid and maleic acid.
 - 64. (New) The isolated polypeptide of Claim 63, wherein the acid is citric acid.
- 65. (New) An isolated polypeptide having an amino acid sequence which consists of the following amino acids:

H-Ser Pro Lys Met Val Gln Gly Ser Gly Cys Phe Gly Arg

Lys Met Asp Arg Ile Ser Ser Ser Gly Leu Gly Cys Lys

Val Leu Arg Arg His-OH

which is in the form of an acid addition salt, wherein the acid is selected from the group consisting of sulfuric acid, formic acid, citric acid, fumaric acid and maleic acid.

- 66. (New) The isolated polypeptide of Claim 65, wherein the acid is selected from the group consisting of citric acid, fumaric acid and maleic acid.
 - 67. (New) The isolated polypeptide of Claim 66, wherein the acid is citric acid.
- 68. (New) An isolated polypeptide having an amino acid sequence which consists of the following amino acids:

H-Gly Ser Gly Cys Phe Gly Arg Lys Met Asp Arg Ile Ser Ser

Ser Ser Gly Leu Gly Cys Lys Val Leu Arg Arg His-OH

which is in the form of an acid addition salt, wherein the acid is selected from the group consisting of sulfuric acid, formic acid, citric acid, fumaric acid and maleic acid.



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Val Leu Arg Arg His-OH

- 69. (New) The isolated polypeptide of Claim 68, wherein the acid is selected from the group consisting of citric acid, fumaric acid and maleic acid.
 - 70. (New) The isolated polypeptide of Claim 69, wherein the acid is citric acid.
- 71. (New) An isolated polypeptide having an amino acid sequence which consists of the following amino acids:

H-Ser Pro Lys Met Val Gln Gly Ser Gly Cys Phe Gly Arg
Lys Met Asp Arg Ile Ser Ser Ser Gly Leu Gly Cys Lys

which is in the form of an acid addition salt, wherein the acid is selected from the group consisting of sulfuric acid, formic acid, citric acid, fumaric acid and maleic acid.

- 72. (New) The isolated polypeptide of Claim 71, wherein the acid is selected from the group consisting of citric acid, fumaric acid and maleic acid.
 - 73. (New) The isolated polypeptide of Claim 72, wherein the acid is citric acid.



SUPPORT FOR THE AMENDMENT

Newly-added Claims 62-73 are supported by the specification at pages 3-26 and by the original claims. No new matter is believed to have been added to the present application by the amendments submitted above.



REMARKS

Claims 36-37 and 62-73 are now pending.

At the outset, Applicants would like to thank the Examiner for indicating that Claims 36 and 37 are allowable. Accordingly, those claims will not be discussed further below.

Favorable reconsideration of Claims 62-73 is respectfully requested.

Claims 62-73 are directed to the recited polypeptide which is in the form of an acid addition salt, where the acid is selected from the group consisting of sulfuric acid, formic acid, citric acid, fumaric acid and maleic acid. See Claims 62, 65, 68 and 71. Each of the dependent claims further define the identity of the acid.

The rejection of the claims under 35 U.S.C. §102(e) over Seilhamer et al., U.S. 5,674,710, is respectfully traversed. That reference fails to describe the claimed polypeptide addition salts.

Seilhamer et al. describe acid addition salts where the acid is hydrochloric acid, phosphoric acid, acetic acid, oxalic acid, tartaric acid or mandelic acid (see column 17, lines 47-55). The reference fails to describe acid addition salts where the acid is sulfuric acid, formic acid, citric acid, fumaric acid or maleic acid. Accordingly, Seilhamer et al. fail to disclose the claimed polypeptides. Withdraw of this ground of rejection is respectfully requested.

The rejection of the claims under 35 U.S.C. §102(e) over Seilhamer et al., U.S. 5,948,761, is respectfully traversed. That reference fails to describe the claimed polypeptide addition salts.

Seilhamer et al. describe acid addition salts where the acid is hydrochloric acid, phosphoric acid, acetic acid, oxalic acid, tartaric acid or mandelic acid (see column 18, lines 13-21). The reference fails to describe acid addition salts where the acid is sulfuric acid, formic acid, citric acid, fumaric acid or maleic acid. Accordingly, Seilhamer et al. fail to



disclose the claimed polypeptides. Withdraw of this ground of rejection is respectfully requested.

The rejection of the claims under 35 U.S.C. §102(e) over Seilhamer et al., U.S. 5,114,923, is respectfully traversed. That reference fails to describe the claimed polypeptide addition salts.

Seilhamer et al. describe acid addition salts where the acid is hydrochloric acid, phosphoric acid, acetic acid, oxalic acid, tartaric acid or mandelic acid (see column 19, lines 35-43). The reference fails to describe acid addition salts where the acid is sulfuric acid, formic acid, citric acid, fumaric acid or maleic acid. Accordingly, Seilhamer et al. fail to disclose the claimed polypeptides. Withdraw of this ground of rejection is respectfully requested.

The rejection of the claims under 35 U.S.C. §103(a) over the Seilhamer et al. patents individually or collectively and Landaburu et al., Dees et al. and Koltitschke et al. is respectfully traversed. Those references fail to suggest the claimed polypeptide addition salts.

As discussed above, the Seilhamer et al. patents fail to describe an acid addition salt where the acid is sulfuric acid, formic acid, citric acid, fumaric acid or maleic acid. There is no suggestion from those patents to use the acids recited in the claimed polypeptide addition salt.

Landaburu et al. disclose lyophilized fibronectin formulations. Dees et al. disclose an injectable pharmaceutical preparation. Koltitschke et al. disclose a coagulant plasma-protein solution. See the Abstract of each patent. None of those references individually or in any combination suggests using sulfuric acid, formic acid, citric acid, fumaric acid or maleic acid to prepare an acid addition salt of the claimed polypeptides.



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In view of the foregoing, the combined disclosure of the Seilhamer et al. patents, Landaburu et al., Dees et al. and Koltitschke et al. fail to suggest the claimed polypeptides. Therefore, Claims 62-73 are not obvious over those references. Accordingly, withdraw of this ground of rejection is respectfully requested.

Applicants submit that the present application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND, MAIER & NEUSTADT, P.C. Norman F. Oblon

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